REMARKS/ARGUMENTS

Claims 1-12 and 23-24 are currently pending. Claims 1 and 5 have been amended. Claims 12-22 directed to a non-elected invention have been canceled. Claim 23 has been tentatively withdrawn. Claim 24 has been added.

According to the Office action, claim 23 has been withdrawn as being directed to an independent and distinct invention. Applicants respectfully traverse the requirement for restriction with respect to claim 23. Claim 23 is directed to a specific embodiment of the invention rather than an independent and distinct invention. Restriction is improper in the present case because search and examination can be made without serious burden even if claim 23 were directed to an independent or distinct invention. See MPEP §803. Therefore, applicants respectfully request that the restriction requirement with respect to claim 23 be withdrawn.

Claims 1 and 5 stand objected to because of the inclusion of parentheses in the claims. Claims 1 and 5 have been amended to eliminate the parentheses objected to by the Examiner. Therefore, applicants respectfully request that the objection to claims 1 and 5 be withdrawn.

Claims 1, 2, 6-9 and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,839,177 ('177). Applicants respectfully submit that the cited reference fails to disclose or suggest the claims of the pending application. According to the Office action, the deposit core of the composition disclosed in the '177 is an immediate release type and the composition provides a release rate falling within some of the limits set forth in claim 1 of the pending application. However, the '177 patent is directed to tablet cores and not multi-particulate pharmaceutical dosage forms as set forth in the claims of the present application. Multi-particulate as used in the claims of the pending application refers to the population of extended release beads and, in accordance with certain claims, the population of immediate release beads. Claim 1 of the pending application refers to a population of extended release beads, wherein the extended release beads comprise an active-containing core particle and an extended release coating comprising a water-insoluble polymer membrane surrounding the core. The '177 patent, by contrast, fails to disclose or suggest a multi-particulate population of

extended release beads. The Office action argues that the '177 composition comprises a plurality of granulates that can be interpreted as being the same as particulates. However, this broad reading of the '177 patent fails to account for the fact that the extended release beads in the present application are each individually coated with an extended release coating surrounding the core of each core particle in the extended release beads. The identification of granulates that are compressed into a tablet form is insufficient to anticipate or render obvious the multi-particulate dosage form set forth in the claims of the pending application. By contrast, the beads of the present application maintain their individuality and perform as individual entities. Each of the beads is individually coated with an extended release coating. The granulates of the '177 patent, by contrast, are compressed into a monolithic structure, wherein the individual particles do not act or perform individually. Furthermore, the uncoated deposit core in the '177 patent fails to act as an immediate release component and the coated deposit core is not a true sustained-release component. For at least these reasons, applicants respectfully submit that the claims of the pending application are novel and non-obvious over the cited reference.

Claim 1 and 2-11 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. According to the Office action, it is unclear whether the newly added term "multi-particulate" refers to either the immediate release or the extended release portions of the pharmaceutical dosage form. Applicants respectfully traverse this rejection for the following reasons. The term "multi-particulate" simply refers to a plurality of particles present in the dosage form. These can be extended release beads, immediate release beads or the combination thereof. Applicants respectfully submit that the term complies with 35 U.S.C. §112 and request that the rejection be withdrawn.

Claims 1-11 stand rejected under 35 U.S.C. §112, first paragraph, as being non-enabling for skeletal muscle relaxants other than cyclobenzaprine. Applicants respectfully submit that one of ordinary skill in the art reading the disclosure in the present application is sufficiently enabled to practice the scope of the invention as set forth in the claims. As indicated in the Office action, the relative skill of those in the art is very high such as a PhD or an MD. Applicants have provided a number of representative examples with respect to cyclobenzaprine hydrochloride, which provide the necessary guidance to one of ordinary skill in the art to practice the invention.

Without undue experimentation, one of ordinary skill in the art would be able to optimize formulations in terms of the selection of the polymer-plasticizer combinations, the composition, membrane thicknesses, etc. to fall within the dissolution specifications set forth in the claims of the pending application. Therefore, applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance and favorable action on the merits is requested. Any questions concerning this application may be directed to applicant's undersigned attorney at the telephone number indicated below.

Respectfully submitted,

John P. Kane, Reg. No. 44,815

THOMPSON HINE L.L.P
2000 Courthouse Plaza NE
10 West Second Street
Dayton, Ohio 45402-1758
(937) 443-6816
#428798 v1